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# Vaccine Development and Manufacturing



**EDITED BY**

**Emily P. Wen • Ronald Ellis • Narahari S. Pujar**

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# Vaccine Development And Manufacturing Wiley Series In Biotechnology And Bioengineering

**Andrea Wilcks, Hector Quemada**



## **Vaccine Development And Manufacturing Wiley Series In Biotechnology And Bioengineering:**

*Vaccine Development and Manufacturing* Emily P. Wen, Ronald J. Ellis, Narahari S. Pujar, 2015 Vaccine Manufacturing and Production will serve as a reference on all aspects of vaccine production by providing an in depth description of the available technologies for making different types of vaccines and the current thinking in facility designs and supply issues This book will provide insight to the issues scientists face when producing a vaccine the steps that are involved and will serve as a reference tool regarding state of the art vaccine manufacturing technologies and facility set up

*Vaccine Development and Manufacturing* Emily P. Wen, Ronald Ellis, Narahari S. Pujar, 2014-11-17 Vaccine Manufacturing and Production is an invaluable reference on how to produce a vaccine from beginning to end addressing all classes of vaccines from a processing production and regulatory viewpoint It will provide comprehensive information on the various fields involved in the production of vaccines from fermentation purification formulation to regulatory filing and facility designs In recent years there have been tremendous advances in all aspects of vaccine manufacturing Improved technology and growth media have been developed for the production of cell culture with high cell density or fermentation Vaccine Manufacturing and Production will serve as a reference on all aspects of vaccine production by providing an in depth description of the available technologies for making different types of vaccines and the current thinking in facility designs and supply issues This book will provide insight to the issues scientists face when producing a vaccine the steps that are involved and will serve as a reference tool regarding state of the art vaccine manufacturing technologies and facility set up Highlights include Comprehensive coverage of vaccine production from a process point of view fermentation to purification to formulation developments from a production point of view from facility design to manufacturing and from a regulatory point of view requirements from government agencies Authors from different major pharmaceutical and biotechnology companies Describes the challenges and issues involved in vaccine production and manufacturing of the different classes of vaccines an area not covered by other books currently on the market

*mRNA Therapeutics* Sarfaraz K. Niazi, 2022-12-06 This book is the most comprehensive and complete treatise on nucleic acid therapeutic products including mRNA vaccines their manufacturing formulations and testing for safety and efficacy Details include cGMP compliant manufacturing and regulatory filing steps A new concept of biosimilar mRNA vaccine is presented to secure fast approval of copies of mRNA vaccines Projections of financial plans to establish RNA manufacturing facilities are provided along with details of supply chain management Finally the future of nucleic acid products in gene therapy and other newer applications is presented along with a perspective that all new vaccines will be the nucleic acid type that will further provide first time prevention of autoimmune disorders It is projected that both big pharma and start ups will enter this field and we can expect significant additions to our drug armamentarium soon

**Mucosal Vaccines** David W. Pascual, 2019-10-19 Mucosal Vaccines Innovation for Preventing Infectious Diseases discusses basic knowledge and discovery in the area of mucosal immunology and its related scientific

fields This completely updated revised and authoritative treatise covers all aspects of mucosal vaccines including their development mechanisms of action molecular cellular aspects and practical applications The book is organized in a unique format with basic clinical and practical aspects described and discussed The accumulated knowledge and new discoveries on the development of mucosal vaccines are logically introduced and discussed in an easy to understand format Provides the latest views on mucosal vaccines Applies basic and current principles in the field of mucosal immunology and related scientific fields e g microbiology infectious diseases systems biology medicine dentistry veterinary medicine and translational research to the development of new vaccines Links basic clinical and practical aspects of mucosal vaccines to different infectious diseases Presents user friendly organization using attractive illustrations

**Application of Omic Techniques to Identify New Biomarkers and Drug Targets for COVID-19** Paul C. Guest,2023-06-28 The COVID 19 pandemic caused by the SARS CoV 2 virus has affected nearly every country and territory in the world Although worldwide vaccination efforts have reduced the risk of serious disease outcomes disparities in distribution have led to multiple waves of SARS CoV 2 outbreaks and the emergence of variants of concern some of which have enhanced infectivity and ability to evade existing vaccines Hence there is an increasing interest in understanding the evolution of viruses like SARS CoV 2 as well as improving our capacity to effectively current and manage future pandemics This new volume reviews the most effective omic techniques for increasing our understanding of COVID 19 to improve diagnostics prognostics and genomic surveillance and to facilitate development of effective treatments and vaccines Chapters are written by an international team of experts and explore methods in the areas of genomics transcriptomics proteomics and metabolomics Techniques used to assess physiological function at the molecular level and artificial intelligence approaches used for more effective validation and translation of biomarker candidates into clinical use are also discussed This book is an excellent resource for researchers studying biomarkers virology metabolic diseases and infectious diseases as well as clinical scientists physicians drug company scientists and healthcare workers

**Bioprocessing Technology for Production of Biopharmaceuticals and Bioproducts** Claire Komives,Weichang Zhou,2018-12-27 Written for industrial and academic researchers and development scientists in the life sciences industry Bioprocessing Technology for Production of Biopharmaceuticals and Bioproducts is a guide to the tools approaches and useful developments in bioprocessing This important guide Summarizes state of the art bioprocessing methods and reviews applications in life science industries Includes illustrative case studies that review six milestone bio products Discusses a wide selection of host strain types and disruptive bioprocess technologies

**Current Developments in Biotechnology and Bioengineering** Vanete Thomaz Soccol,Ashok Pandey,Rodrigo R. Resende,2016-09-17 Current Developments in Biotechnology and Bioengineering Human and Animal Health Applications provides extensive coverage of new developments state of the art technologies and potential future trends presenting data based scientific knowledge and information on medical biotechnological interventions for human and animal health Drawing

on the key development areas in this field the book reviews biotechnological advances and applications in immunotechnology vaccines and vaccinology combinatorial libraries gene and cell therapy tissue engineering and parasite and infectious disease diagnostics This title outlines why biotechnological techniques in these areas are useful in a clinical context and considers their potential uses limitations and the ethical considerations surrounding their use Provides development in human and animal health due to biotechnology Includes immunotechnology and vaccinology Outlines diagnostic techniques based on tissue and metabolic engineering principles Considers potential uses of the various biotechnology based techniques and the ethical issues raised in their use

**Biopharmaceutical Processing** Gunter Jagschies,Eva Lindskog,Karol Lacki,Parrish M. Galliher,2018-01-18 Biopharmaceutical Processing Development Design and Implementation of Manufacturing Processes covers bioprocessing from cell line development to bulk drug substances The methods and strategies described are essential learning for every scientist engineer or manager in the biopharmaceutical and vaccines industry The integrity of the bioprocess ultimately determines the quality of the product in the biotherapeutics arena and this book covers every stage including all technologies related to downstream purification and upstream processing fields Economic considerations are included throughout with recommendations for lowering costs and improving efficiencies Designed for quick reference and easy accessibility of facts calculations and guidelines this book is an essential tool for industrial scientists and managers in the biopharmaceutical industry Offers a comprehensive go to reference for daily work decisions Covers both upstream and downstream processes Includes case studies that emphasize financial outcomes Presents summaries decision grids graphs and overviews for quick reference

**Preparative Chromatography for Separation of Proteins** Arne Staby,Anurag S. Rathore,Satinder Ahuja,2017-03-06 Preparative Chromatography for Separation of Proteins addresses a wide range of modeling techniques strategies and case studies of industrial separation of proteins and peptides Covers broad aspects of preparative chromatography with a unique combination of academic and industrial perspectives Presents Combines modeling with compliance using of Quality by Design QbD approaches including modeling Features a variety of chromatographic case studies not readily accessible to the general public Represents an essential reference resource for academic industrial and pharmaceutical researchers

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aspects Describes industrial bioprocesses based on the reaction media Lists the type of bioreactors used for a specific bioprocess application Outlines the principles of control systems in various bioprocesses

**Bioreactor Design Concepts for Viral Vaccine Production** Surajbhan Sevda,Sachin Kumar,2024-05-12 Bioreactor Design Concepts for Viral Vaccine Production covers a range of interdisciplinary chapters from the engineering perspective of bioreactor design to the biotechnological perspectives of vector design for vaccine development The book covers bioreactor concepts such as static systems single use systems stirred tanks perfusion wave and packed beds It reviews options for efficient and economical production of human vaccines and discusses basic factors relevant for viral antigen production in mammalian cells avian cells and insect cells This book will be a great resource for those interested in implemented novel bioreactor design or experimental schemes towards intensified or and enhanced vaccine production Covers the fundamentals of bioreactor designs Provides strategies for designing a successful vector based vaccine Discusses the applications of biological kinetics thermodynamics and basic substrate requirements for viral vaccine production

Process Validation in Manufacturing of Biopharmaceuticals Anurag Singh Rathore,Hal Baseman,Scott Rudge,2023-12-18 The fourth edition of Process Validation in Manufacturing of Biopharmaceuticals is a practical and comprehensive resource illustrating the different approaches for successful validation of biopharmaceutical processes A pivotal text in its field this new edition provides guidelines and current practices contains industrial case studies and is expanded to include in depth analysis of the new Process Validation PV guidance from the US FDA Key Features Offers readers a thorough understanding of the key concepts that form the basis of a good process validation program for biopharmaceuticals Includes case studies from the various industry leaders that demonstrate application of these concepts Discusses the use of modern tools such as multivariate analysis for facilitating a process validation exercise Covers process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing including chromatography chemical modification reactions ultrafiltration and microfiltration and practical methods to test raw materials and in process samples Providing a thorough understanding of the key concepts that form the basis of a good process validation program this book will help readers ensure that PV is carried out and exceeds expectations Fully illustrated this is a much needed practical guide for biopharmaceutical manufacturers

**Microbial Biotechnology** Kay Yeoman,Beatrix Fahnert,David Lea-Smith,Tom Clarke,2021 La 4e de couverture indique In this title a team of microbiologists explore how microbial biotechnology and its applications are fundamental to our way of life They explain microbial growth and how this relates to food biotechnology as well as a number of other microbial products from fine chemicals to pharmaceuticals examine ethical and societal factors and consider the future of microbial biotechnology in the context of advances being made in synthetic biology

Policy and Regulation in Bioengineering and Biotechnology Andrea Wilcks,Hector Quemada,2023-12-13

Emerging Non-Clinical Biostatistics in Biopharmaceutical Development and Manufacturing Harry Yang,2016-11-30 The premise of Quality by Design QbD is that the quality of the pharmaceutical

product should be based upon a thorough understanding of both the product and the manufacturing process This state of the art book provides a single source of information on emerging statistical approaches to QbD and risk based pharmaceutical development A comprehensive resource it combines in depth explanations of advanced statistical methods with real life case studies that illustrate practical applications of these methods in QbD implementation

### **Comprehensive Biotechnology**

,2011-08-26 The second edition of Comprehensive Biotechnology Six Volume Set continues the tradition of the first inclusive work on this dynamic field with up to date and essential entries on the principles and practice of biotechnology The integration of the latest relevant science and industry practice with fundamental biotechnology concepts is presented with entries from internationally recognized world leaders in their given fields With two volumes covering basic fundamentals and four volumes of applications from environmental biotechnology and safety to medical biotechnology and healthcare this work serves the needs of newcomers as well as established experts combining the latest relevant science and industry practice in a manageable format It is a multi authored work written by experts and vetted by a prestigious advisory board and group of volume editors who are biotechnology innovators and educators with international influence All six volumes are published at the same time not as a series this is not a conventional encyclopedia but a symbiotic integration of brief articles on established topics and longer chapters on new emerging areas Hyperlinks provide sources of extensive additional related information material authored and edited by world renown experts in all aspects of the broad multidisciplinary field of biotechnology Scope and nature of the work are vetted by a prestigious International Advisory Board including three Nobel laureates Each article carries a glossary and a professional summary of the authors indicating their appropriate credentials An extensive index for the entire publication gives a complete list of the many topics treated in the increasingly expanding field

### **Micro- and Nanotechnologies-Based Product Development** Neelesh Kumar Mehra,Arvind Gulbake,2021-09-06

This book provides comprehensive information of the nanotechnology based pharmaceutical product development including a diverse range of arenas such as liposomes nanoparticles fullerenes hydrogels thermally responsive externally activated theranostics TREAT hydrogels microspheres micro and nanoemulsions and carbon nanomaterials It covers the micro and nanotechnological aspects for pharmaceutical product development with the product development point of view and also covers the industrial aspects novel technologies stability studies validation safety and toxicity profiles regulatory perspectives scale up technologies and fundamental concept in the development of products Salient Features Covers micro and nanotechnology approaches with current trends with safety and efficacy in product development Presents an overview of the recent progress of stability testing reverse engineering validation and regulatory perspectives as per regulatory requirements Provides a comprehensive overview of the latest research related to micro and nanotechnologies including designing optimisation validation and scale up of micro and nanotechnologies Is edited by two well known researchers by contribution of vivid chapters from renowned scientists across the globe in the field of pharmaceutical sciences Dr Neelesh

Kumar Mehra is working as an Assistant Professor of Pharmaceutics Biopharmaceutics at the Department of Pharmaceutics National Institute of Pharmaceutical Education Research NIPER Hyderabad India He received TEAM AWARD for successful commercialisation of an ophthalmic suspension product He has authored more than 60 peer reviewed publications in highly reputed international journals and more than 10 book chapter contributions He has filed patents on manufacturing process and composition to improved therapeutic efficacy for topical delivery He guided PhD and MS students for their dissertations research projects He has received numerous outstanding awards including Young Scientist Award and Team Award for his research output He recently published one edited book Dendrimers in Nanomedicine Concept Theory and Regulatory Perspectives in CRC Press Currently he is editing books on nano drug delivery based products with Elsevier Pvt Ltd He has rich research and teaching experience in the formulation and development of complex innovative ophthalmic and injectable biopharmaceutical products including micro and nanotechnologies for regulated market Dr Arvind Gulbake is working as an Assistant Professor at the Faculty of Pharmacy School of Pharmaceutical Population Health Informatics at DIT University Dehradun India He has authored more than 40 peer reviewed publications in highly reputed international journals four book chapters and a patent contribution He has received outstanding awards including Young Scientist Award and BRG Travel Award for his research He is an assistant editor for IJAP He guided PhD and MS students for their dissertations research projects He has successfully completed extramural project funded by SERB New Delhi Government of India He has more than 12 years of research and teaching experience in the formulation and development of nanopharmaceuticals

**Protein Instability at Interfaces During Drug Product Development** Jinjiang Li, Mary E. Krause, Raymond Tu, 2021-02-12

Proteins are exposed to various interfacial stresses during drug product development They are subjected to air liquid liquid solid and sometimes liquid liquid interfaces throughout the development cycle from manufacturing of drug substances to storage and drug delivery Unlike small molecule drugs proteins are typically unstable at interfaces where on adsorption they often denature and form aggregates resulting in loss of efficacy and potential immunogenicity This book covers both the fundamental aspects of proteins at interfaces and the quantification of interfacial behaviors of proteins Importantly this book introduces the industrial aspects of protein instabilities at interfaces including the processes that introduce new interfaces evaluation of interfacial instabilities and mitigation strategies The audience that this book targets encompasses scientists in the pharmaceutical and biotech industry as well as faculty and students from academia in the surface science pharmaceutical and medicinal chemistry areas

**Biosimilars and Interchangeable Biologics** Sarfaraz K. Niazi, 2016-01-05 What s the Deal with Biosimilars Biosimilars are gaining momentum as new protein therapeutic candidates that can help fill a vital need in the healthcare industry The biological drugs are produced by recombinant DNA technology that allows for large scale production and an overall reduction time in costs and development Part of a two volume set th *Industrial Microbiology and Biotechnology* Pradeep Verma, 2024-11-19 This book is a comprehensive guide for industrial bioprocess development



covering major aspects of microbial processes and their role in biotechnology It provides a selection of hyperproducers microbial products and metabolic engineering strategies for industrial production It covers high cell density cultivation techniques product formation kinetics measurement and limiting parameters in large scale process development The first and second section of the book focuses on biotechniques including spectroscopic concepts of light wave and electromagnetic theory as well as absorption fluorescence phosphorescence infrared and Raman spectroscopy It also covers the basic principles concepts biological applications and other advanced techniques The third section emphasizes microbial inventions and improvements in bioprocess development It covers microbial products and recent developments in fermentation technology and also includes information on metabolic engineering The fourth section related to microbial inventions and bioprocesses which include platforms for recombinant gene expression as well as the development of recombinant heterologous expression systems such as E coli yeast mammalian and insect cells and plant cells used as biofactories The fifth section of the book focuses on microbial product waste management in extreme environments biomass waste management bio pulping bio bleaching textiles biofuels and animal feed production The book aims to provide a multidisciplinary opportunity on all aspects of microbial biotechnology It covers recent international developments that have renewed interest in industrial microbiology and biotechnology The book is suitable for teachers researchers graduate and post graduate students environmentalists microbiologists and biotechnologists

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